REMARKS

Applicant thanks the Office for the attention accorded the present Application in the November 23, 2007, Office Action. In that Action, Claims 1, 2 and 5 were objected to for informalities, Claims 1 and 5 were rejected under 35 USC §102(b) as being anticipated by Millenson (EP 0 717 283 A2), and Claims 2-3 were rejected under 35 USC §103(a) as being unpatentable over Millenson in view of Zwanziger et al. (WO 95/33996).

Applicant has amended Claims 1 and 5 to correct the informalities as suggested by the Office except that Applicant has used the word "said" instead of "the" in order to keep the terminology consistent with usage in the claims.

Applicant traverses the Office's objection to Claim 2 for informalities. Claim 2 uses a Markush group to limit the selection of the risk markers. The proper format of a Markush group includes the words "selected from the group consisting of." The Office suggests changing the terms "the group" to "a group," which is contrary to the prescribed wording for a proper Markush group. In light of the preceding argument, Applicant respectfully requests that the objection as to Claim 2 be withdrawn.

35 USC §102(b) rejections:

The Office has rejected Claims 1 and 5 under 35 USC §102(b) as being anticipated by Millenson. The Office states that Millenson discloses a diagnostic and directed medication system that is capable of minimizing a potential adverse drug reaction to a prescribed medical therapy as broadly claimed by Applicant. Applicant

respectfully traverses.

Applicant has amended Claims 1 and 5 to include the limitations in Applicant's drug metabolism test component and the prescription instruction component. The drug metabolism test component of the directed medication system includes the limitation to identify one or more risk markers in the user's biological sample that predicts a high probability of organ dysfunction that can cause an adverse drug reaction to a prescribed medical therapy. Additionally, the prescription instruction component was amended to clearly indicate that it is a written prescription instruction component. Support for this can be found in Fig. 1 and paragraph [0039].

The written prescription instruction component of the directed medication system includes the limitation that the prescription instruction component has a first instruction to obtain the drug metabolism test component and follow the test component instructions for submitting a sample for testing and a second instruction that directs the user to obtain a prescribed medical therapy that contains a prescription for a medication based on the result of the test where the medication is selected to minimize the probability of an adverse drug reaction being caused by the user taking the prescribed medication.

It should be noted that most medical test kits on the market today are used for determining events that have already occurred. (See Applicant's disclosure, paragraph [0006]). Applicant's directed medication system, however, is a system to predict the potential for an adverse medical event before a medical event occurs (i.e., an adverse drug reaction). Specifically, Applicant's directed medication system determines those

medications that could cause a bad reaction in a user to a medication taken by the user thereby enabling one to avoid or minimize such a reaction caused by the medication. Applicant's directed medication system is a proactive testing system, not a reactive testing system.

The Millenson device is a diagnostic instrument for use in detecting a foreign element in a blood sample. Specifically, it is a test kit to test for the presence of the HIV virus. This test, like most medical test kits on the market, is used to determine an event that has already occurred. The event that has already occurred is the contraction of the HIV virus, which is known to cause AIDS. There is no known cure for the disease.

In contrast, Applicant's test kit/system is not used to determine a foreign element in a user's biological sample. It is also not used to determine an event that has already occurred. Applicant's test kit/system is used to determine the presence of the risk markers in a user's biological sample, which are not foreign elements but are naturally occurring in the user's biological makeup, that foretell the likelihood of an event occurring in the future if certain medications are prescribed to and taken by the user. In other words, Applicant's test kit/system will determine those medications that, if taken by the user, would likely produce an adverse drug reaction in the user. Consequently, a safer drug can be prescribed for a particular condition while minimizing the probability that the drug/medication itself would cause an adverse medical event.

Applicant's claimed invention includes a test component for receiving the user's biological sample and a written prescription instruction component that contains a first instruction and a second instruction. The first instruction directs the user to obtain the

test component and follow the instructions provided with the test component for submitting the user's biological sample. The second instruction directs the user to obtain a prescribed medical therapy that includes a prescription for a medication based on the test result of the test component where the medication selected is chosen to minimize the probability of an adverse drug reaction being caused by the prescribed medication.

Millenson discloses a test component specific for determining the presence of the HIV virus but not a written prescription instruction component that instructs the user to obtain a prescribed medical therapy that includes a prescription for a medication based on the test result.

Anticipation is established only when a single prior art reference discloses, expressly or under the principles of inherency, each and every element of the claimed invention. The Millenson reference does not disclose a prescription instruction component that instructs the user to obtain a prescribe medical therapy that includes a prescription for a medication whose selection is based on the test results of the test component and minimizes the probability of an adverse drug reaction being caused by the selected medication when taken by the user. The Millenson reference discloses only a diagnostic test kit for the determination of the presence of a foreign element in the blood, i.e. HIV virus.

Where the Millenson reference fails to disclose expressly or under the principles of inherency a written prescription instruction component as claimed by Applicant, the Millenson reference cannot anticipate Applicant's amended Claims 1 and 5.

In light of the above amendments and arguments, Applicant respectfully submits that the 35 USC §102(b) rejection of Claims 1 and 5 has been successfully traversed. Allowance of these claims is therefore requested.

35 USC §103(a) rejections:

The Office has rejected Claims 2 and 3 under 35 USC §103(a) as being unpatentable over Millenson in view of Zwanziger et al. (WO 95/33996). The Office states that Millenson discloses the claimed diagnostic and directed medication system as set forth in the rejection for anticipation but fails to teach the one or more predefined drug metabolism markers being DNA or enzymes or the test component being a genomics-based test. The Office further states that Zwanziger teaches the drug metabolism markers being DNA or enzymes and the test component being a genomics-based test. The Office concludes that all of the component parts are known in Millenson and Zwanziger and that it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the components as taught by Millenson with the components taught by Zwanziger to achieve the predictable results providing alternate diagnostic testing means in a diagnostic and directed medication system.

Applicant respectfully traverses.

Applicant reincorporates Applicant's arguments as they pertain to Millenson where Millenson fails to disclose a written prescription instruction component and where the Millenson is a test (1) to determine the presence of a foreign element in the blood

and (2) to determine an event that has already occurred (i.e., contraction of the HIV virus).

The Zwanziger device is a home test kit that a user must use and then call the test center to obtain the results of the test. The Zwanziger home test kit is a chromatographic test kit that provides an indication of the presence or absence of a particular disease or physiological condition. The home test kit is an assay system that receives a sample from the user. The assay system produces a coded pattern indicative of the presence of or a different coded pattern indicative of the absence of a disease or physiological condition. Again, like Millenson, the Zwanziger device is a test (1) to determine the presence of a foreign element in the blood and (2) to determine an event that has already occurred (i.e., contraction of the HIV virus or other listed viruses/infections).

The Zwanziger test kit instructions only provide the user with instructions on how to obtain a blood sample, place it on the sample area of the test kit, and to call the testing center with the test kit code and color coding to receive the results of the test. Upon completing the test, the user must then make a telephone call to an interpretation center, disclose the test pattern along with a test kit identifier assigned to the assay system, and receive an interpretation of the coded pattern from the interpretation center. The user, while on the telephone call, may also receive verbal counseling, which may be appropriate in view of the interpretation of the coded pattern.

Zwanziger, like Millenson, fails to disclose a written prescription instruction component as a part of the test kit.

On the other hand, Applicant's directed medication system is **not** a test system (1) to determine the presence of a foreign element in the user's biological sample and (2) to determine an event that has already occurred (i.e., the presence or absence of a particular disease or physiological condition).

Applicant's claimed directed medication system is to determine whether a user's natural, biological makeup is susceptible to dysfunction caused by particular medications. Applicant's claimed directed medication system is a designed to determine whether the patient, who is prescribed a medication used to treat a particular disease or physiological condition that the patient already knows exists, is more prone to have an adverse drug reaction to the medication if taken by the patient. Depending on the test results, the healthcare provider for the user can modify or change the medical therapy to minimize the potential for an adverse drug reaction.

In addition, Millenson's and Zwanziger's and Applicant's devices are quite different in the problems to be solved. One would use either the Millenson or the Zwanziger device to determine the presence or absence of a foreign element in the blood (i.e. a particular disease or physiological condition) and, once determined to be present, then one could use Applicant's claimed invention to determine if the usually prescribed medical therapy (i.e. the medication(s)) would cause an adverse drug reaction requiring a modification or customization of the medical therapy. One would not use Applicant's claimed invention to determine the presence or absence of a particular disease or physiological condition.

The Zwanziger disclosure fails to disclose not only a written prescription

instruction component but also a second instruction that directs the user to obtain a prescribed medical therapy containing a prescription for a medication that minimizes the probability of organ dysfunction that can lead to an adverse drug reaction.

In light of the above amendments and arguments, Applicant respectfully submits that the 35 USC §103(a) rejection of Claims 2 and 3 have been successfully traversed. Allowance of these claims is therefore requested.

Where Claim 1 is deemed to be generic, Applicant also respectfully requests the reinstatement of Claims 4 and 6-19 of the Group 1 invention and allowance of these claims.

Applicant believes that all of the examined claims should now be in condition for allowance as well as the withdrawn claims of the Group 1 invention. Early and favorable action is respectfully requested.

The Examiner is invited to telephone the undersigned, Applicant's attorney of record, to facilitate advancement of the present application.

Respectfully submitted,

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